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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER

BORIN, MICHAEL L

| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,044

Applicant(s)

SAMPSON ET AL.

Examiner

Michael Borin

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11-13, 21, 57-59, 62 and 63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11-13, 21, 57-59, 62 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of Claims

1. Response to restriction requirement filed 07/22/2005 is acknowledged. Applicant elected, with traverse, Group I, claims 1-4,11,12,21,62,63. The specific reasons for traverse are not presented in the applicant's response. Examiner maintains that methods of Groups I and II are patentably distinct because they are directed to methods which have different modes of operation and different steps. The method of Group II requires treating test sites in the presence of the sample to extend oligonucleotide probes to include a detector agent. Contrary, the method of Group I utilizes sensors covalently coupled to redox active moieties. The methods require applying different prior art and have different enablement requirements. Applicant provided general discussion, but no specific reasons for traverse. The restriction requirement is still deemed proper and is therefore made FINAL. Claims 57-59 are withdrawn from further consideration by the examiner, 37 CFR.1.142(b), as being drawn to a non-elected groups. Cancellation of claims 57-59 is requested.

Base claims 1,12 are amended to be limited to non-enzymatic ligands. Consequently, the art rejection over De Lumley-Woodyear is withdrawn, and new ground of rejection is applied.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

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by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1-4,11,12,21,62,63 are rejected under 35 U.S.C. 102(e) as being anticipated by Choong et al. (US Patent 6,518,024).

The claims are directed to a method for detecting a target molecule, said method comprising bringing a plurality of electrodes supported by a semiconductor substrate into proximity with a reaction medium comprising a sample with the target molecule, wherein electrodes comprise at least one target probe, wherein the probe is with or without a ligand attached to it and the probe has a redox active moiety attached thereto; selectively addressing plurality of cells within the substrate to apply a stimulus to activate a predetermined redox active moiety, and to detect the presence or absence of the target molecule in the sample.

Choong et al, first, review state of the art and teach that one known method for detecting a target nucleic acid molecule is to use an electrochemical tag (or label) such as a redox moiety in combination with an electrochemical detection means such as cyclic voltammetry. The selective covalent modification of nucleic acids can be achieved using redox-active moieties such as transition metal complexes of transition metals. The specificity of redox intercalator methods is often much worse than can be achieved with covalently-bound redox tags. See col. 2, line 41 through col. 3, line 16. Further, Choong et al describe their improved method for detecting a target molecule, said method comprising bringing a plurality of electrodes supported by a semiconductor substrate into proximity with a reaction medium comprising a sample with the target molecule, wherein the array of oligonucleotide probes is immobilized to a surface of the

electrode. The sequence of each oligonucleotide at each particular identified position (or "address") in the array is known and at least one of said oligonucleotides is complementary to a sequence in a nucleic acid contained in the biological sample to be assayed (termed the "target" or "target nucleic acid"). The probes have redox labels attached to them. Any electrochemically-distinctive redox label which does not interfere with the incorporation of the ddNTP into a nucleotide chain is preferred. See col. 3,4, 8, claims 1-4.

3. Claims 1-4,11,12,21,62,63 are rejected under 35 USC 103(a) as being unpatentable over Blackburn et al. The rejection is maintained for the reasons of record.

Response to arguments

It seems that applicant's arguments address mostly claim 57 which is now withdrawn from consideration. As to claims 1 and 12, applicant argues, that Blackburn method involves interacting multiple probes per target molecule, while the claimed method requires interaction of "one probe per one target sequence". First, the latter is not correct as the claims are directed to interaction of pluralities of molecules, namely "target molecule or target molecules" with "at least target probe". The same is stated in Blackburn wherein the method comprises interacting "at least a first primer nucleic acid" to the "target sequence" to form [singular] hybridization complex.

The rejection is maintained.

Prior art of record

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 5,874,046 teaches sensor system which includes a highly-sensitive, highly-selective sensor cell that comprises a single-stranded oligonucleic acid sequence that is complementary to a portion of the DNA of a target live microorganism and is modified with the covalent attachment of redox moieties

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb
09/30/2005